NHS
Harrogate and Rural District
Clinical Commissioning Group

Commissioning Policy

Treatment	**Gastroelectrical Stimulation (GES) / Gastric Neuromodulation**
For the treatment of	**Severe Gastroparesis**
Background	In April 2013 NHS England took over responsibility for the decision making for GES for severe gastroparesis, under the Specialist Services Commissioning programme, in order to address the varied commissioning positions across the county. However, in February 2014 it was confirmed that this procedure is now outside the commissioning responsibility of NHS England and, therefore, decisions have been returned to the responsibility of local Clinical Commissioning Groups (CCGs). Since then, NICE have issued further guidance on the safety and efficacy of Gastroelectrical Stimulation for Gastroparesis (IPG 489)[1]. This policy sets out the criteria that must be met for a case to be considered by the IFR Panel for GES treatment for severe gastroparesis.
Commissioning position	All requests for this treatment must be sent to the CCG IFR Panel for consideration. Gastric neuromodulation for gastroparesis is only commissioned by NHS Harrogate and Rural CCG if the following criteria apply: • Patients suffer who suffer from diabetic or idiopathic gastroparesis (defined by gastric emptying studies and assessed as part of an MDT) AND • The symptoms of gastroparesis are chronic, severe and debilitating (ie Grade 3) with evidence of impact affecting quality of life (eg poor diabetic control) AND • Symptoms are refractory to all previous treatments including dietary modifications, drug treatment (prokinetics and antiemetics) AND • Patients require additional nutritional support (feeding tube or total parenteral nutrition [TPN]) AND • The only remaining treatment option would be resectional surgery (gastrectomy) AND

	• The Provider is able to fulfil NICE IPG 489 recommendations including MDT assessment. Implantation of permanent GES will only be commissioned where the insertion of a temporary GES has, after at least 48 hours (usually up to 2 weeks), resulted in a significant improvement in gastroparesis symptoms as per symptom diary and agreed by MDT. If temporary pacing has been unsuccessful and wire slippage is suspected, then a second temporary pacing can be considered. **There will be a maximum of two cases commissioned per year who meet the above criteria.** Patients who do not fulfil the above criteria will be considered only in exceptional cases.
Effective from	Aug 2014
Summary of evidence / rationale	Gastroparesis is a chronic disorder of the stomach in which food empties from the stomach much more slowly than normal in the absence of any type of obstruction. The most common symptoms are nausea and protracted vomiting. Other symptoms include abdominal bloating, pain and, in severe cases, malnutrition. There is currently no cure for gastroparesis and treatment is aimed at symptom relief. Gastroparesis symptoms have a highly negative impact on patients' quality of life and ability to perform regular activities, including work. Management of severe symptoms involves significant costs both to patients and health services. GES has been shown to: • Reduce nausea and vomiting by more than 50% in almost 80% of patients • Improve quality of life • Improve glucose control in diabetic patients • Reduce the use of nutritional support, health care costs and need for hospitalisations In Gastric Neuromodulation, electrical stimulation is delivered via an implanted system that consists of a neurostimulator and two leads. Initially, temporary GES is conducted under sedation involving the insertion of a temporary wire into the gastric mucosa .The wire is attached to a neuromodulator worn on a belt. After 2 days, gastric scintigraphy is used to assess the improvement in gastric emptying. Patients showing improved symptoms proceed to have

	the permanent stimulator fitted. Under general anaesthesia, the stimulating electrode of each intramuscular lead is fixed to the muscle of the lower stomach. The connector end of each lead is then attached to the neurostimulator, which is placed in a small pocket in the abdominal wall via a surgical incision. When the neurostimulator is turned on, electrical impulses are delivered. A programmer can adjust the rate and amplitude of stimulation. NICE recommendations are that: 1. Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit. 2. During the consent process, clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device. 3. Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units. 4. Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful. The Enterra GES system is the only commercially available product. The price for a complete Enterra system is £8,250 plus VAT and carriage. Surgical and hospital costs have to be added on top of this. Local costs for the Enterra system are around £7000, with £3500 tariff. Temporary pacing wires cost £150. No cost effectiveness studies were identified. However, the North East Treatment Advisory Group produced a costing study in response to a request from the North East Specialised Commissioning Team in 2010. Their report estimated that the cost for implantation of an Enterra™ device is between £16,000 and £18,000 per patient. This included all pre- and postoperative care but noted that additional costs could arise from the treatment of complications. There was potential to reduce costs of antiemetic medication and hospital admissions.
Date	July 2014
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References

[1] http://www.nice.org.uk/Guidance/IPG489 (accessed 08 July 2014)